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HAMRE, SCHUMANN, MUELLER & LARSON, P.C.
P.O. BOX 2902
MINNEAPOLIS, MN 55402-0902

EXAMINER	
DIETERLE, JENNIFER M	

ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/539,421	YAMAOKA, HIDEAKI	
	Examiner	Art Unit	
	Jennifer Dieterle	4111	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4 and 7-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4 and 7-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/22/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Applicant's amendment of 6/9/2009 does not render the application allowable.

Comments

1. The objections to the drawings have been overcome by Applicant's amendments thereof.

2. The objections to the specification have been overcome by Applicant's amendments thereof.

3. The objections to claims 11 and 17 have been overcome by Applicant's amendments thereof.

Status of Claims

Claims 2, 3, 5 and 6 have been canceled.

Claims 1, 4, 11, 17 and 18 have been amended.

Claims 1, 4, and 7-18 are being addressed in this action.

Status of the Rejections

4. All rejections from the previous office action are withdrawn in view of Applicant's amendment. New grounds of rejections under 35 U.S.C. 103(a) are necessitated by amendments. Hodges (WO 2003/032411, pub date April 17, 2003, printed in English) and Heller (US 6,143,164) are being cited and relied on for the first time in this office action. Its use was necessitated by the amendment to the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4 and 7-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Regarding claim 1, claim 1 defines a reaction space that is "no greater than 45 micrometers". Given this statement, it leaves open the possibility of the reaction space being zero (i.e. non-existent). Therefore, given Applicants' specification at paragraph [0049] which states, "if the facing distance H1 is too small, the blood cannot be properly moved inside the reaction space." Therefore, a space of zero would not allow for proper blood flow in the reaction space and therefore render the device inoperable. Additionally, Applicants' state at paragraph [0049] and in their examples (see Table 1) that the minimal space required for the function of their device is 25 micrometers. Regarding claims 4 and 7-18, since these claims are dependent on claim 1, they are also rejected.

Therefore, a space of anything less than 25 micrometers is not enabled by Applicants' specification and a space of zero would not allow for proper blood flow in the reaction space and therefore render the device inoperable.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1, 4 and 7-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claim 1, Applicants refer to "one of said first and second electrodes" and continues to refer to "said one electrode" to define the electron release region. It is not clear as to which electrode (the first or second) Applicants are referring too rendering claim 1 vague and ambiguous. Regarding claims 4 and 7-18, since these claims are dependent on claim 1, they are also rejected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1, 4, 7, 8, 12 and 18 are rejected under 35 U.S.C. 103(a) as being obvious over Gotoh et al. (U.S. Pat. No. 6,071,391) in view of and as evidenced by Hodges (WO 2003/032411) or Heller (US 6,143,164).

Regarding claims 1 and 4, Gotoh et al. teaches thin analysis tool for measuring glucose comprising:

- A first plate 2 formed with a first 3 and second 4 electrodes (figure 15, col. 1, lines 62-63; col. 16, lines 33-35);
- A second plate facing the first and second electrodes of the first plate (col. 1, lines 59-67).
- a reaction space for holding a sample liquid 5 (figure 15);
- a reagent portion that dissolves when the sample is held in the space (col. 14, lines 45-60); the first and second surfaces face each other (col. 17, lines 17-19) spaced at a distance;
- a voltage is applied between the electrodes to facilitate the redox reaction which will inherently create a region around the electrode in which electrons are released (col. 15, line 62).

Gotoh et al. does not teach that the reaction space be no greater than 45 micrometers as stated in claim 1, or between 25 and 45 micrometers as stated in claim

Hodges teaches an electrochemical sensor comprising multiple electrodes and a mediator for the determination of analyte (glucose) in a sample (page 3, lines 13-20; figure 2). Hodges teaches a that a first and second layer can be spaced less than about

500 micrometers apart, preferably less than about 450, 400, 350, 300, or 250 micrometers apart, more preferably less than about 200, 150, or 100 micrometers apart, and most preferably less than about 90, 80, 70, 60, 50, 40, 30, 25, 20, 15, 10, 5 or 1 micrometers (page 11, lines 11-22). Hodges teaches that this spacing can be used in figure 2 in which the electrodes are located on the same plane. (page 11, lines 20-22; page 7, lines 21-27; figure 2). The spacing being selected to maintain the separation of the electrodes, thereby providing a sample reservoir in the electrochemical cell that has a smaller volume of space which facilitates a corresponding higher amplification factor (page 7, lines 28-31).

Heller et al. also teach a small volume electrochemical sensor for the determination of glucose (abstract). Heller et al. teach a measurement zone is contained within this sample chamber and is the region of the sample chamber that contains only that portion of the sample that is interrogated during the analyte assay. (col. 9. lines 62-67). Additionally, Heller et al. teach that the reaction space is less than preferably about 0.05 mm (50 micrometers) or less. (col. 10, lines 50-54). Heller et al. teach that a small reaction chamber is preferable because the thickness is small to promote rapid electrolysis of the analyte, as more of the sample will be in contact with the electrode surface for a given sample volume. In addition, a thin sample chamber helps to reduce errors from diffusion of analyte into the measurement zone from other portions of the sample chamber during the analyte assay, because diffusion time is long relative to the measurement time. (col. 10, lines 38-54).

Therefore, it would have been obvious to one skilled in the art to modify the reaction chamber size of Gotoh et al. to be less than about 45 micrometers or between 25 and 45 micrometers as taught by Hodges or Heller et al. because a smaller volume of space which facilitates a corresponding higher amplification factor (Hodges page 7, lines 28-31) and a smaller chamber will help to reduce errors from diffusion of analyte into the measurement zone from other portions of the sample chamber during the analyte assay, because diffusion time is long relative to the measurement time. (Heller et al. col. 10, lines 38-54).

Additionally, in view of Gotoh's et al. general description (see col. 3, lines 39-44) of the distance between the surfaces being 100μm - 500μm, it is not inventive to discover the optimum or workable ranges by routine experimentation. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The discovery of an optimum value of a known result effective variable, without producing any new or unexpected result, is within the ambit of a person of ordinary skill in the art. See *In re Boesch*, 205 USPQ 215 (CCPA 1980)(see MPEP § 2144.05, II). As evidenced above by Heller et al. and Hodges, it is well known in the art to select/optimize a reaction chamber size based on the desire to reduce errors from diffusion of analyte into the measurement zone from other portions of the sample chamber during the analyte assay, because diffusion time is long relative to the measurement time (Heller et al. col. 10, lines 38-54) or to use a

smaller volume of space which facilitates a corresponding higher amplification factor (Hodges page 7, lines 28-31) depending on the outcome desired.

Therefore, it would have been obvious to a person of ordinary skill in the art to select an appropriate distance between the electrodes of Gotoh et al. to establish the size of the reaction chamber.

Regarding claim 7, Gotoh et al. teaches a thin analyzing device but does not expressly teach the use of capillary force to move the sample.

However, it is well known in the glucose sensor art that analyte in a glucose sensor is moved by capillary force. Heller et al. evidences that either capillary action is the known way to move analyte in a sensor and also teach that a sorbent material can be used to facilitate the uptake of small volume samples by a wicking action and may complement (or even replace) the capillary action of the sample chamber (col. 10, lines 55-60). Hodges evidences that a sample to be admitted to the sensor can be drawn in by wicking or capillary action (page 10, lines 23-24).

Official notice has been taken of the fact that capillary force to move a sample in a glucose sensor is asserted to be "common knowledge." (MPEP 2144.03). Therefore, it would have been obvious to one of ordinary skill in the art that the analyte in Gotoh et al. is moved by capillary forces that may even be further enhanced by the use of sorbent material as evidenced by Heller et al. or Hodges above.

Regarding claim 8, Gotoh et al. teaches that the reagent portion includes an electron mediator and a redox enzyme (col. 4, lines 6-16).

Regarding claim 12, Gotoh et al. teaches that the redox enzyme has glucose dehydrogenation activity (col. 7, lines 11-13).

Regarding claim 18, Gotoh et al. teach thin analysis tool for measuring glucose (col. 1, lines 38-40). Gotoh et al. teach the device can be used for the measuring of blood sugar or urine (col. 13, lines 44-46).

7. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gotoh et al. and Hodges (WO 2003/032411) or Heller (US 6,143,164), in view of Leong et al. (U.S. Pat. No. 6,837,988).

Regarding claim 9, Gotoh et al. teaches a thin analyzing device, but does not teach the use of ruthenium as the electron mediator.

Leong et al. recognizes that a ruthenium compound can be used as a mediator agent (col. 11, lines 50-60).

The Courts have held that the selection of a known material, which is based upon its suitability for the intended use, is within the ambit of one of ordinary skill in the art. See *In re Leshin*, 125 USPQ 416 (CCPA 1960) (see MPEP § 2144.07). The simple

substitution of one known element for another is likely to be obvious when predictable results are achieved. See *KSR International Co. v. Teleflex Inc.*, 550 U.S. __,__, 82 USPQ2d 1385, 1395 – 97 (2007) (see MPEP § 2143 B)

Therefore, it would have been obvious to one of ordinary skill in the art to have substituted the known functionally equivalent ruthenium compound taught by Leong et al. for the electron mediator of Gotoh et al. because Loeng et al. shows that either ruthenium complexes or ferricyanide may be utilized as mediator agents (col. 11, lines 50-60).

8. Claims 10, 11 and 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gotoh et al. and Hodges (WO 2003/032411) or Heller (US 6,143,164) and Leong et al., in view of Nagakawa et al. (WO 03/025558, with reference to it English equivalent, U.S. Pat. No. 7,390,391).

Regarding claims 10, 11 and 13-17, Gotoh et al. teach a thin analyzing device, but do not teach that the X in the ruthenium compound could be NH_3, a halogen ion, CN, pyridine, nicotinamide, or H_2O and that n^+ is the valence of an oxidized Ru(III) complex determined by a type of X. In addition, Gotoh et al. do not teach that the molecular weight of cytochrome C is about 43 kDa and the subunit of glucose dehydrogenase has a molecular weight of about 60 kDa measured by SDS-polyacrylamide gel electrophoresis.

Nagakawa et al. teach that a ruthenium compound could be NH_3 or a halogen ion (col. 3, lines 63-67: col. 4, lines 1-4). Nagakawa et al. also teach that the microbe may

belong to the Burkholderia genus (col. 4, line 57). In addition, Nagakawa et al. teach that the molecular weight of cytochrome C is about 43 kDa (col. 4, lines 43-45) and the molecular weight of GDH is about 60 kDa (col. 4, lines 38-39). Nagakawa et al. teach that the new materials reduced background current (col. 2, lines 62-65).

The Courts have held that the selection of a known material, which is based upon its suitability for the intended use, is within the ambit of one of ordinary skill in the art. See *In re Leshin*, 125 USPQ 416 (CCPA 1960) (see MPEP § 2144.07). In addition, the combination of familiar elements is likely to be obvious when it does no more than yield predictable results. Furthermore, the simple substitution of one known element for another is likely to be obvious when predictable results are achieved. See *KSR International Co. v. Teleflex Inc.*, 550 U.S. __,__, 82 USPQ2d 1385, 1395 – 97 (2007) (see MPEP § 2143).

Therefore, it would have been obvious to one of ordinary skill in the art to have modified the electron mediator and enzyme of Gotoh et al. to be a ruthenium compound where X is NH_3 or a halogen ion (belonging to the genus Burkholderia) having the molecular weight of cytochrome C is about 43 kDa and the molecular weight of GDH is about 60 kDa as taught by Nagakawa et al. because the new materials reduced background current (col. 2, lines 62-65).

Response to Arguments

Applicant's arguments with respect to claims 1, 4 and 7-18, filed 6/9/2009, have been fully considered but they are not persuasive.

9. Applicant's response that Gotoh (US 6,071,391) is silent in regards to an electron release region is acknowledged, but is unpersuasive. It is well known in the glucose sensor art that a glucose sensor basic function is to supply a current and when the reduction mediator comes within a range of the working electrode it releases electrons and the reaction based on the mediator allows for the measurement of the concentration of the analyte of interest (Applicants' specification paragraph [0004] discusses background art disclosing the basic known function of a glucose sensor). Therefore, to be operational, Gotoh inherently has an "electron release" region as do all glucose sensors.

10. With regard to Applicants' argument concerning the facing distance that is no greater than 45 micrometers and that it would require more than mere optimization to discover the optimum range of no greater that 45 micrometers is unpersuasive. It is common knowledge in the sensor art that the size of a reaction space can be optimized based on the specie of interest in the sample or the chemical reaction of interest to optimize the time, sample size, or current necessary for the reaction to proceed. Applicants' provide no prima facie evidence showing a new or unexpected result as a result of a reaction chamber being 45 micrometers or 100 micrometers. Arguments of counsel cannot take the place of factually supported objective evidence. See, e.g., *In re Huang*, 100 F.3d 135, 139-40, 40 USPQ2d 1685, 1689 (Fed. Cir. 1996); *In re DeBlauwe*, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984)(MPEP 2145).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dieterle whose telephone number is (571) 270-7872. The examiner can normally be reached on Monday thru Friday, 8am to 5pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Sines can be reached on (571) 272-1263. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JMD
8/4/09

/Brian J. Sines/

Supervisory Patent Examiner, Art Unit 1795